

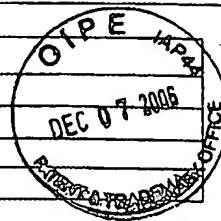
**Complete if Known**

**FIRST  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	10/754,711
Filing Date	January 12, 2004
First Named Inventor	Deborah Kim GLENCROSS
Examiner Name	A. FORD
Attorney Docket No.	1025455-000113



## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

## NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
af	Ian Storie et al., "Flow Rate Calibration II: A Clinical Evaluation Study Using PanLeucoGating as a Single-Platform Protocol", Clinical Cytometry, 55B:8-13 (2003).
af	D.K. Glencross et al., "Results from the WHO/NHLS/QASI CD4 Regional External Quality Assessment Scheme (REQAS): Multi-Site Evaluation of CD4 Technology Performance", 2 <sup>nd</sup> South African AIDS Meeting, June 2005.
af	W. Stevens et al., "Affordable HIV Diagnosis and Monitoring for Scaling Up ARV Treatment Programmes", The Southern African Journal of HIV Medicine, September 2005, pages 38-41.
af	L. Scott et al., "Monitoring Reproducibility of Single Analysis, Single Platform CD4 Cell Counts in a High Volume, Low Resource Laboratory Setting Using Sequential Bead Count Rates", Clinical Cytometry, 67B:31-32 (2005).

Examiner Signature	<i>Alison S.</i>	Date Considered	<i>18 December 2006</i>
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**FIRST**  
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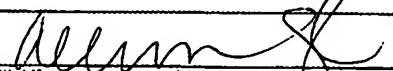
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Sheet 2 of 2

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af	T. Rehle et al., "HIV-positive educators in South African public schools", Education Labour Relations Council, 2005.
af	T. Rehle et al., "Appendix and Addenda - HIV-positive educators in South African public schools", Education Labour Relations Council, 2005.
af	NCCLS, "Clinical Applications of Flow Cytometry: Quality Assurance and Immunophenotyping of Lymphocytes; Approved Guideline", 1998, Abstract, Vol 18; No. 21, page H42-A.
af	U.S. Food and Drug Administration, "Recognized Consensus Standards", <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.CFM?Standard%20identification%20NO-10448">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.CFM?Standard identification NO-10448</a> , MARCH 30, 2006.
af	G. Vercauteren et al., "Impact of Who External Quality Assessment (EQA) programme on the laboratory performance of CD4 enumeration for monitoring of ARV therapy in Resource Limited settings", World Health Organization, Conference: AIDS2006 (Abstract), (2006).
af	D. Glencross et al., "Improved between-laboratory performance of South African NHLS laboratories using PLG CD4 methodology for the national antiretroviral (ARV) treatment programme", University of the Witwatersrand, August 14, 2006 (Abstract).
af	D. Glencross et al., "CD45-Assisted PanLeucogating for Accurate, Cost-Effective Dual-Platform CD4+ T-Cell Enumeration", Cytometry (Clinical Cytometry) 50: 69-77 (2002).
af	M. Willja et al., "Less Expensive CD4+ T Cell Monitoring Using Panleucogating", AIDS 2002 Barcelona, July 7-12, 2002 (Abstract).
af	K. Pattanapanyasat et al., "A Multicenter Evaluation of the PanLeucogating Method and the Use of Generic Monoclonal Antibody Reagents for CD4 Enumeration in HIV-Infected Patients in Thailand", Cytometry Part B (Clinical Cytometry) 65B: 29-36 (2005).
af	K. Pattanapanyasat et al., "Low-Cost CD4 Enumeration in HIV-Infected Patients in Thailand", Asian Pacific Journal of Allergy and Immunology, 21: 105-113 (2003).
af	T. Denny et al., "Determination of CD4 and CD8 Lymphocyte Subsets by a New Alternative Fluorescence Immunoassay", Clinical and Diagnostic Laboratory Immunology, May 1995, p. 330-336.
af	L. Scott et al., "Antiviral Therapy 8 (suppl 1) Abstract No. 1226", 2 <sup>nd</sup> International AIDS Conference on HIV Pathogenesis and Treatment, France, 2003.
af	T. Denny et al., "A Multi-Lab Study of CD4 Counts Using Flow Cytometric PanLeukoGating (PLG): A Naid-Daids Immunology Quality Assessment Program Study", 13 <sup>th</sup> Conference Retrovirology and Opportunistic Infection (CROI), Boston, Feb. 2006.
af	N. Sippy et al., "Comparison of the Panleucogating technique with four-color heterogenous gating for CD4+ T cell enumeration by flowcytometry in HIV-1 infected individuals in Barbados", Ladymeade Reference Unit, Ministry of Health, Barbados. No Date.

Examiner Signature		Date Considered	18 December 2006
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